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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,533	09/21/2001	Stuart Neville Farrow	PG3600USW	3391

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EXAMINER

MONDESI, ROBERT B

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/868,533

Applicant(s)

FARROW ET AL.

Examiner

Robert B. Mondesi

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21-36 is/are pending in the application.
- 4a) Of the above claim(s) 27-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

Applicants' election of Invention XI, Claims 21-26, in response to the restriction requirement mailed August 14, 2006 is acknowledged. Because applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Therefore the requirement is still deemed proper and is made FINAL.

### ***Status of the claims***

**Claims 1-20** have been canceled. **Claims 21-36** are pending. **Claims 27-36** are withdrawn for pertaining to nonelected subject matter. **Claims 21-26** are presently under examination.

### ***Priority***

The current application filed on September 21, 2001 is a 371 of PCT/EP99/07303 filed on 10/05/1999, which in turn claims priority to foreign application, UNITED KINGDOM 9828628.9 filed on 12/23/1998. A certified copy of foreign document UNITED KINGDOM 9828628.9 has been provided.

### ***Preliminary Amendment***

The preliminary amendments filed June 19, 2001 and February 6, 2006 have been entered.

### ***Drawings***

Drawings filed June 19, 2001 have been accepted.

***Information Disclosure Statement***

The IDS filed June 19, 2001 has not been accepted because none of the cited references have been provided.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the breadth of the claims, (2) the nature of the invention, (3) the state of the prior art, (4) the

Art Unit: 1652

predictability or unpredictability of the art, (5) the relative skill of those in the art, (6) the amount or direction or guidance presented, (7) the presence or absence of working examples, and (8) the quantity of experimentation necessary. Although the quantity of experimentation alone is not dispositive in a determination of whether the required experimentation is undue, this factor does play a central role. For example, a very limited quantity of experimentation may be undue in a fledgling art that is unpredictable where no guidance or working examples are provided in the specification and prior art, whereas the same amount of experimentation may not be undue when viewed in light of some guidance or a working example or the experimentation required is in a predictable established art. Conversely, a large quantity of experimentation would require a correspondingly greater quantum of guidance, predictability and skill in the art to overcome classification as undue experimentation. In *Wands*, the determination that undue experimentation was not required to make the claimed invention was based primarily on the nature of the art, and the probability that the required experimentation would result in successfully obtaining the claimed invention. (*Wands*, 8 USPQ2d 1406). Thus, a combination of factors which, when viewed together, would provide an artisan of ordinary skill in the art with an expectation of successfully obtaining the claimed invention with additional experimentation would preclude the classification of that experimentation as undue. A combination of *Wands* factors, which provide a very low likelihood of successfully obtaining the claimed invention with additional experimentation, however, would render the additional experimentation undue.

1-2 .Breadth of the claims and the nature of the invention..

Art Unit: 1652

In regards to the method of the invention and the breadth of the claims the broadest interpretation that applies is a method for identifying a compound that decreases binding between a protein comprising a polypeptide of Seq ID No. 1 or 2 and the protein's receptor expressed on B cells, the method comprising contacting said protein and said B cell receptor in the presence of a test compound, where a decrease in binding of the protein to the receptor, compared to that which would occur in the absence of said test compound, indicates said test compound decreases the binding of the protein and the receptor.

3-4. The state of prior art and the level of predictability in the art.

The prior art does not discuss any test compounds that decrease the binding between a protein comprising the amino acid of SEQ ID NO:1 or 2 and its receptor.

5. The relative skill in the art.

The relative skill in the art as it relates to the method of the invention is characterized by that of a M.D. or Ph. D. level individual.

6-7. The amount of guidance present and the existence of working examples.

The applicant has not provided any guidance as to what to what compounds would be tested in order to decrease the binding of the protein comprising the amino acid sequence of SEQ ID NO: 1 or 2.

There are no existing examples in the specification of the present application that would indicated the use of a particular test compound for the inhibition or decrease of the binding of the protein of the invention and its receptor.

8. The quantity of experimentation necessary.

The amount of experimentation that is required is undue: while testing for compounds that inhibit proteins from binding their receptors are routine, a method of testing particular compounds that inhibit a specific protein such as a protein comprising the amino acid sequence of SEQ ID NO: 1 or 2 is not routine and requires more experimentation. Therefore, in view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, and the high degree of unpredictability as evidenced by the prior art, undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention.

It must be noted that the issue in this case is the breath of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. The Applicants make and test position is inconsistent with the decisions of *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) where it is stated that "... scope of claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary skill in the art...". Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). Therefore, for the instant specification to be enabling, it needs to provide direction/guidance regarding an acceptable number of different test compounds that inhibit the interaction of a protein comprising the amino acid sequence of SEQ ID NO:6.

Art Unit: 1652

Absent sufficient guidance/direction one of skill in the art would not be able to practice the claimed invention commensurate in scope with the claims. Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention as the amount of experimentation required is undue, due to the broad scope of the claims, the lack of guidance and insufficient working examples provided in the specification and the high degree of unpredictability as evidenced by the state of the prior art, attempting to test all the different types of compounds encompassed by the claimed invention would constitute undue experimentation. Therefore, applicants have not provided sufficient guidance to enable one of skill in the art to make and use the claimed invention in a manner that reasonably correlates with the scope of the claims, to be considered enabling.

**Claims 21 and 23-26** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In **claim 21** applicants have cited a "protein comprising a polypeptide of SEQ ID NO: 1". This phrase is not in accordance with art recognized language when discussing proteins and polypeptides. A protein cannot comprise a polypeptide. If anything, a polypeptide comprises a protein. Applicants should refrain from using such language when indicating that a polypeptide or a protein comprises a particular SEQ ID NO:. Applicants are advised to utilize language that has been used in claim 22, as in. a



Art Unit: 1652

protein or a polypeptide comprising an amino acid sequence of a particular SEQ ID NO:  
such as SEQ ID NO: 1 or 2.

**Claims 23-26** are dependent claims that do not remedy the deficiencies of the  
dependent claims that they depend from

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the  
examiner should be directed to Robert B. Mondesi whose telephone number is 571-  
272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's  
supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax  
phone number for the organization where this application or proceeding is assigned is  
571-273-8300.

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USPTO Customer Service Representative or access to the automated information  
system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert B Mondesi  
Examiner  
Art Unit 1652

  
11-1-06

ROBERT B. MONDESI  
PATENT EXAMINER